



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,259	12/28/2001	Steven S. Bachand	2843	8123

23693 7590 05/18/2005

Varian Inc.  
Legal Department  
3120 Hansen Way D-102  
Palo Alto, CA 94304

EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/033,259

Applicant(s)

BACHAND, STEVEN S.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

20

DETAILED ACTION

1. Applicant's amendment filed 25 February 2005 has been received. Claims 19-22 have been canceled. Claims 1-18 are pending.
2. The indicated allowability of claims 1-5 is withdrawn in view of the newly discovered references. Rejections based on the newly cited reference(s) follow.

*Claim Rejections - 35 USC § 112, First paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite that the non-absorbent medium allows a liquid sample to mix with the dry reagent as the sample passes *through* the non-absorbent medium. This limitation is not supported by the specification as originally filed. The specification does not make clear the definition of "passing through", thus, it is open to the broadest reasonable interpretation; in which case, liquid sample is seen to

Art Unit: 1641

pass *through* (i.e. *top to bottom*) the non-absorbent medium. This recitation is not supported by the specification.

*Claim Rejections - 35 USC § 112, Second paragraph*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it does not make clear the location of the dry reagent. It is suggested that Applicant amend the claims as follows to obviate the 112, first and second paragraph rejections as well as the art rejection and to place the claims in conditions for allowance:

Claim 1. A binding assay device comprising:  
a porous membrane comprising a material enabling capillary movement of a liquid sample from a first area of the membrane to a second area of the membrane;  
a detection site disposed on the membrane between the first and second areas;  
a non-absorbent medium disposed on the membrane between said detection site and the membrane first area, the medium being attached to the membrane by an adhesive; and  
a dry reagent adhered only to the underside of [disposed between] the non-absorbent medium [and the membrane], wherein the liquid sample passing by capillarity along the non-absorbent medium is mixed with the dry reagent [passing through the non-absorbent medium] and a mixed sample is absorbed into the membrane before reach said detection site.

Claims 2 and 6 should be canceled if claim 1 is amended as suggested above.

Claim 11 is indefinite because several terms lack antecedent support. It is suggested that claim 11 be amended as follows:

Claim 11. A method of producing a binding assay device, said method comprising the steps of:

providing a porous membrane comprising a material enabling capillary movement of a liquid sample from a first area of the membrane to a second area of the membrane;

disposing a detection site on the membrane between the first and second areas;

providing a non-absorbent medium having a bottom side with an adhesive disposed on the bottom side;

disposing a particle based reagent onto the [medium] bottom side of the non-absorbent medium;

evaporating a solvent in the particle based reagent to provide a dry reagent on the [medium] bottom side of the medium; and

adhering the medium [bottom side] to the membrane between the first area [said] and the detection site.

Claim 12. The method according to claim 11 wherein the [non-porous] non-absorbent medium is provided with adhesive covering a center [medium] of the bottom side of the medium and the [the] particle based reagent is disposed onto the adhesive.

### *Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by May et al (US 5,602,040).

Claim 1 is directed to a device comprising a porous membrane having a detection site and a non-absorbent medium disposed on the membrane. The device further comprises a dry reagent disposed between the non-absorbent medium and the porous membrane. This device is fully disclosed by May.

May teaches a device comprising a porous membrane having a labeled zone and a detection zone disposed such that sample passes through the labeled zone before reaching the detection zone. In one embodiment, May teaches that a transparent moisture-impermeable plastic material covers the porous membrane. In this instant, the dry reagent (i.e. labeled binding partner) is disposed *between* the non-absorbent material and the porous membrane. See column 2, lines 3-20 and column 12, lines 27-40.

*Allowable Subject Matter*

9. Claims 6-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims as suggested above.

The following is a statement of reasons for the indication of allowable subject matter: Claim 6-18 define over the prior art of record because the prior art of record fails to teach or make obvious an immunochromatographic device where dry reagents are disposed only to the underside of a non-absorbent medium and the non-absorbent

Art Unit: 1641

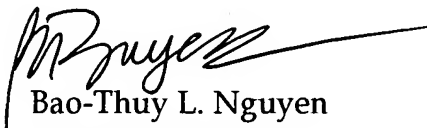
medium is adhered to a porous membrane placing the dry reagent between the non-absorbent medium and the porous membrane.

*Conclusion*

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
5/16/05